Initial Approval: July 26, 2017
Revised Dates: October 11, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi™)

CRITERIA FOR INITIAL APPROVAL OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of Sofosbuvir/Velpatasvir/Voxilaprevir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC) (hepatitis C virus [HCV])
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m^2) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not be on concurrent direct acting hepatitis C agents
- Patient must meet one of the following:
    - Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
    - Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir WITHOUT an NS5A inhibitor
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
    - Advanced fibrosis (Metavir F3)
    - Compensated cirrhosis (Child-Pugh A)
    - Organ transplant
    - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
    - Proteinuria
    - Nephrotic syndrome
    - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with sofosbuvir/velpatasvir/voxilaprevir therapy
- For all genotypes: the PDL preferred drug, which covers that specific genotype, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines
- Patient must be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment
- Patient must not be on concurrent rifampin
- Patient should not be on concurrent:
    - P-gp inducers
    - Moderate to potent CYP2B6, 2C8, or 3A4 inducers
    - Amiodarone (if alternative, viable treatment options are unavailable, cardiac monitoring is recommended)

RENEWAL CRITERIA FOR SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR:

- Prescriber must document adherence by patient of greater than or equal to 90%

LENGTH OF APPROVAL FOR SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR: 4 weeks for a **total of 12 weeks of treatment**

Notes:

- NS5A inhibitors: daclatasvir, elbatasvir, ledipasvir, ombitasvir, velpatasvir
- Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
_____	_____
DATE	DATE